

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted

Protocol summary

Study aim

Determining the effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted to Beasat hospital in Sanandaj, 2019

Design

Clinical trials with control group, available sampling and randomized sampling using the Pack envelopes containing letters A and B

Settings and conduct

This study will be carried out in the high risk mothers section of Beasat Hospital in Sanandaj. Intervention in people who entered the intervention group, will be in such a way that for 4 consecutive days each day for 10 minutes at 6-4 pm in a room that has the usual conditions of massage, including dim light, a relaxed place and a suitable chair Will be given massage by the researcher. During the study, patients in the control group will not undergo any other intervention except for the usual treatments.

Participants/Inclusion and exclusion criteria

Mothers with gestational diabetes mellitus with a mild to severe anxiety score (20 and above) based on the Spielberger anxiety inventory

Intervention groups

Intervention group: The diabetic mothers are admitted to the high-risk department of Besat Hospital in Sanandaj, which in addition to receiving usual care during admission, for 4 days, receive 10 minutes a day stroke back massage . Control group: The diabetic mothers admitted to the high-risk department of Besat Hospital in Sanandaj, which received routine care during admission and will not receive any massage.

Main outcome variables

Anxiety; Physiological index including heart rate, blood pressure, respiratory rate, body temperature, blood Sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042464N1**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

trefa mehri

Name of organization / entity

Medical university of kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 44 4433 0566

Email address

mehri.t@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-07-06, 1398/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted

Public title

The effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Second and third trimester of pregnancy The second day of hospitalization Women with gestational diabetes

Exclusion criteria:

history of spinal cord injury or surgery Any skin and bone disorders in the neck, back and sacrum High-risk pregnancies such as multiple pregnancies Heart disease, kidney disease, asthma and depression

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization: Using a packet containing letters A and B. The units were randomly assigned to the packets containing letters A and B in one of the groups of intervention group (A) or control (B) using a simple envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee medical university of kurdistan

Street address

Pasdaran Boulevard, Medical University of Kurdistan

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2019-01-18, 1397/10/28

Ethics committee reference number

IR.MUK.REC.1397.312

Health conditions studied

1

Description of health condition studied

Gestational diabet, anxiety, stroke back massage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The level of anxiety in diabetic pregnant Women in the Spielberger Questionnaire

Timepoint

Before the intervention, the fourth day of the intervention, 2 and 4 days after the end of the intervention

Method of measurement

Spielberger Anxiety Inventory

2

Description

Blood pressure

Timepoint

Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement

Using a pressure gauge

3

Description

Heart beat

Timepoint

Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement

Using the clock, the number is counted in a minute by the researcher

4

Description

Number of breaths

Timepoint

Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement

Using the clock, the number is counted in a minute by the researcher

5

Description

Body temperature

Timepoint

Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement

Using a thermometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Diabetic mothers are admitted to the high risk department of Besat Hospital in Sanandaj, who receive regular care for 4 days at the time of admission and receive 10 minutes a day for back stroke massage every day.

Category

Other

2

Description

Control group: Diabetic mothers are admitted to the high-risk section of Besat Hospital in Sanandaj, who receive routine care during admission and do not receive any massage.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat hospital

Full name of responsible person

trefa mehri

Street address

Keshavarz Street, Meroux Crossroads

City

Sanandaj

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Kurdistan

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6618634683

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besathospital@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Farzin Rezaee

Street address

Kurdistan University of Medical Sciences, Pasdaran Blvd

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Trefa Mehri

Position

Midwifery Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available